

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

TEVA PHARMACEUTICALS USA, INC.,  
TEVA PHARMACEUTICAL INDUSTRIES  
LTD., TEVA NEUROSCIENCE, INC.  
and YEDA RESEARCH AND  
DEVELOPMENT CO. LTD.,

*Plaintiffs,*

v.

SANDOZ INC., SANDOZ  
INTERNATIONAL GMBH,  
NOVARTIS AG, and MOMENTA  
PHARMACEUTICALS, INC.,

*Defendants.*

Civil Action No. 08-CV-7611 (BSJ) (AJP)

TEVA PHARMACEUTICALS USA, INC.,  
TEVA PHARMACEUTICAL INDUSTRIES  
LTD., TEVA NEUROSCIENCE, INC.,  
and YEDA RESEARCH AND  
DEVELOPMENT CO. LTD.,

*Plaintiffs,*

v.

MYLAN PHARMACEUTICALS INC., MYLAN  
INC., and NATCO PHARMA LTD.,

*Defendants.*

Civil Action No. 09-CV-8824 (BSJ) (AJP)

~~PROPOSED~~ FINAL JUDGMENT ORDER

This matter having come before the Court upon the Complaint of Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Inc., Teva Neuroscience, Inc., and Yeda Research and Development Co. (collectively, "Plaintiffs") alleging that Sandoz Inc. and Momenta Pharmaceuticals, Inc. (collectively, the "Sandoz Defendants") infringe U.S. Patent Nos. 7,199,098 ("the '098 patent"), 6,939,539 ("the '539 patent"), 6,054,430 ("the '430 patent"), and 6,620,847 ("the '847 patent") pursuant to 35 U.S.C. §§ 271(a), 271(b), 271(c), and 271(e)(2); Plaintiffs' claims seeking a declaratory judgment of the Sandoz Defendants' infringement of the '098 patent, the '539 patent, the '430 patent, and the '847 patent; and the Sandoz Defendants' counterclaims seeking a declaratory judgment of non-infringement, unenforceability, and invalidity of the '098 patent, the '539 patent, the '430 patent, the '847 patent, U.S. Patent No. 5,981,589 ("the '589 patent"), U.S. Patent No. 6,342,476 ("the '476 patent"), U.S. Patent No. 6,362,161 ("the '161 patent"), U.S. Patent No. 5,800,808 ("the '808 patent"), and U.S. Patent No. 6,048,898 ("the '898 patent") pursuant to 35 U.S.C. §§ 271(a), 271(b) and 271(c); and upon the Complaint of Plaintiffs alleging that Mylan Pharmaceuticals Inc., Mylan Inc., and Natco Pharma Ltd. (collectively, the "Mylan Defendants") infringe the '098 patent, the '539 patent, the '430 patent, the '847 patent, the '589 patent, the '476 patent, and the '161 patent pursuant to 35 U.S.C. §§ 271(a), 271(b), 271(c), and 271(e)(2); Plaintiffs' claims seeking a declaratory judgment of the Mylan Defendants' infringement of the '098 patent, '539 patent, the '430 patent, the '847 patent, the '589 patent, the '476 patent, and the '161 patent pursuant to 35 U.S.C. §§ 271(a), 271(b), and 271(c); and the Mylan Defendants' counterclaims seeking a declaratory judgment of non-infringement, unenforceability, and invalidity of the '098 patent, the '539 patent, the '430 patent, the '847 patent, the '589 patent, the '476 patent, the '161 patent, the '808 patent, and the '898 patent pursuant to 35 U.S.C. §§ 271(a), 271(b) and 271(c),

IT IS on this 23<sup>rd</sup> day of July

1. ORDERED AND ADJUDGED for the reasons set forth in the Court's Opinion dated June 22, 2012, that FINAL JUDGMENT IS ENTERED IN FAVOR OF PLAINTIFFS and AGAINST THE SANDOZ DEFENDANTS with respect to Plaintiffs' claims that the product which is the subject of the Sandoz Defendants' ANDA No. 90-218 infringes claims 1 and 8 of the '098 patent, claims 1, 8, 9, 10, 12, 23, 30, and 31 of the '539 patent, claims 1 and 2 of the '430 patent, and claims 1 and 6 of the '847 patent pursuant to 35 U.S.C. § 271(e)(2)(A), and that each of these asserted claims against the Sandoz Defendants is valid, enforceable, and infringed;
2. IT IS FURTHER ORDERED AND ADJUDGED that FINAL JUDGMENT IS ENTERED IN FAVOR OF PLAINTIFFS and AGAINST THE SANDOZ DEFENDANTS with respect to Plaintiffs' declaratory judgment claims pursuant to 35 U.S.C. §§ 2201, 2202, that the product which is the subject of the Sandoz Defendants' ANDA No. 90-218 if commercially manufactured, used, marketed, sold, or offered for sale within the United States or imported thereto would infringe claims 1 and 8 of the '098 patent, claims 1, 8, 9, 10, 12, 23, 30, and 31 of the '539 patent, claims 1 and 2 of the '430 patent, claims 1 and 6 of the '847 patent against the Sandoz Defendants pursuant to 35 U.S.C. §§ 271(a), (b), and (c), and IT IS DECLARED that each of these asserted claims against the Sandoz Defendants is valid, enforceable, and infringed;
3. IT IS FURTHER ORDERED AND ADJUDGED that FINAL JUDGMENT IS ENTERED IN FAVOR OF PLAINTIFFS and AGAINST THE SANDOZ

DEFENDANTS with respect to the Sandoz Defendants' counterclaims seeking declaratory judgment of non-infringement, invalidity and unenforceability of claims 1 and 8 of the '098 patent, claims 1, 8, 9, 10, 12, 23, 30, and 31 of the '539 patent, claims 1 and 2 of the '430 patent, claims 1 and 6 of the '847 patent, claim 1 of the '589 patent, claim 1 of the '476 patent, claim 1 of the '161 patent, claim 1 of the '808 patent, and claims 1 and 2 of the '898 patent, all such counterclaims are DISMISSED WITH PREJUDICE, and IT IS DECLARED that each of these asserted claims against the Sandoz Defendants is valid, enforceable, and infringed by the product which is the subject of the Sandoz Defendants' ANDA No. 90-218;

4. IT IS FURTHER ORDERED AND ADJUDGED that FINAL JUDGMENT IS ENTERED IN FAVOR OF PLAINTIFFS and AGAINST THE MYLAN DEFENDANTS with respect to Plaintiffs' claims that the product which is the subject of the Mylan Defendants' ANDA No. 91-646 infringes claims 1 and 8 of the '098 patent, claims 1, 8, 9, 10, 12, 23, 30, and 31 of the '539 patent, claims 1, 2, and 3 of the '430 patent, claims 1 and 6 of the '847 patent, claim 1 of the '589 patent, claim 1 of the '476 patent, and claim 1 of the '161 patent pursuant to 35 U.S.C. §271(e)(2)(A), and that each of these asserted claims against the Mylan Defendants is valid, enforceable, and infringed;
5. IT IS FURTHER ORDERED AND ADJUDGED that FINAL JUDGMENT IS ENTERED IN FAVOR OF PLAINTIFFS and AGAINST THE MYLAN DEFENDANTS with respect to Plaintiffs' declaratory judgment claims pursuant to pursuant to 35 U.S.C. §§ 2201, 2202, that the product which is the subject of

the Mylan Defendants' ANDA No. 91-646 if commercially manufactured, used, marketed, sold, or offered for sale within the United States or imported thereto would infringe claims 1 and 8 of the '098 patent, claims 1, 8, 9, 10, 12, 23, 30, and 31 of the '539 patent, claims 1, 2, and 3 of the '430 patent, claim 1 of the '589 patent, claim 1 of the '476 patent, claim 1 of the '161 patent, claims 1 and 6 of the '847 patent against the Mylan Defendants pursuant to 35 U.S.C. §§ 271(a), (b), (c), and IT IS DECLARED that each of these asserted claims against the Mylan Defendants is valid, enforceable, and infringed;

6. IT IS FURTHER ORDERED AND ADJUDGED that FINAL JUDGMENT IS ENTERED IN FAVOR OF PLAINTIFFS and AGAINST THE MYLAN DEFENDANTS with respect to the Mylan Defendants' counterclaims seeking declaratory judgment of non-infringement, invalidity, and unenforceability of claims 1 and 8 of the '098 patent, claims 1, 8, 9, 10, 12, 23, 30, and 31 of the '539 patent, claims 1, 2, and 3 of the '430 patent, claim 1 of the '589 patent, claim 1 of the '476 patent, claim 1 of the '161 patent, claim 1 of the '808 patent, claims 1 and 6 of the '847 patent, and claims 1, 2, and 3 of the '898 patent, all such counterclaims are DISMISSED WITH PREJUDICE, and IT IS DECLARED that each of these asserted claims against the Mylan Defendants is valid, enforceable, and infringed by the product which is the subject of the Mylan Defendants' ANDA No. 91-646;
7. IT IS FURTHER ORDERED that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by the U.S. Food and Drug Administration ("FDA") of the Sandoz Defendants' ANDA No. 90-218 shall not be earlier than



the expiration of the '098 patent, the '539 patent, the '589 patent, the '476 patent, the '161 patent, the '430 patent, and the '847 patent on May 24, 2014, or, to the extent the FDA determines that a pediatric exclusivity is applicable, the date any such exclusivity ends, but that Plaintiffs will provide written notice to the Sandoz Defendants of such grant of pediatric exclusivity within five (5) days of receiving award of exclusivity from the FDA;

8. IT IS FURTHER ORDERED that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by the FDA of the Mylan Defendants' ANDA No. 91-646, shall not be earlier than the expiration of the '098 patent, the '539 patent, the '589 patent, the '476 patent, the '161 patent, the '430 patent, and the '847 patent on May 24, 2014, or, to the extent the FDA determines that a pediatric exclusivity is applicable, the date any such exclusivity ends, but that Plaintiffs will provide written notice to the Mylan Defendants of such grant of pediatric exclusivity within five (5) days of receiving award of exclusivity from the FDA;
9. IT IS FURTHER ORDERED that, pursuant to 35 U.S.C. § 271(e)(4)(B), the Sandoz Defendants and each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with any of them are permanently enjoined from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the product which is the subject of the Sandoz Defendants' ANDA No. 90-218, which infringes claims 1 and 8 of the '098 patent, claims 1, 8, 9, 10, 12, 23, 30, and 31 of the '539 patent, claim 1 of the '589 patent, claim 1 of the '476

patent, claim 1 of the '161 patent, claims 1 and 2 of the '430 patent, and claims 1 and 6 of the '847 patent until May 24, 2014;

10. IT IS FURTHER ORDERED that, pursuant to 35 U.S.C. § 271(e)(4)(B), the Mylan Defendants, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with any of them are permanently enjoined from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the product which is the subject of the Mylan Defendants' ANDA No. 91-646, which infringes claims 1 and 8 of the '098 patent, claims 1, 8, 9, 10, 12, 23, 30, and 31 of the '539 patent, claim 1 of the '589 patent, claim 1 of the '476 patent, claim 1 of the '161 patent, claims 1, 2, and 3 of the '430 patent, and claims 1 and 6 of the '847 patent until May 24, 2014;

11. IT IS FURTHER ORDERED that, pursuant to 35 U.S.C. § 283, the Sandoz Defendants, their respective officers, directors, employees, agents, successors, affiliates and assigns, and all persons and entities acting in concert or participation with them are permanently enjoined from directly or indirectly engaging in the commercial manufacture, use, marketing, sale, or offer for sale within the United States, or from importing into the United States, of the product which is the subject of the Sandoz Defendants' ANDA No. 90-218 until the expiration of the '808 patent on September 1, 2015, and are permanently enjoined from directly or indirectly engaging in the commercial manufacture, use, marketing, sale, or offer for sale within the United States, or from importing into the United States, of the product which is the subject of the Sandoz Defendants' ANDA No. 90-218 until

the expiration of the '098 patent, the '539 patent, the '430 patent, the '589 patent, the '476 patent, the '161 patent, the '847 patent, and the patent '898 patent on May 24, 2014;

12. IT IS FURTHER ORDERED that, pursuant to 35 U.S.C. § 283, the Mylan Defendants, their respective officers, directors, employees, agents, successors, affiliates and assigns, and all persons and entities acting in concert or participation with them are permanently enjoined from directly or indirectly engaging in the commercial manufacture, use, marketing, sale, or offer for sale within the United States, or from importing into the United States, of the product which is the subject of the Mylan Defendants' ANDA No. 91-646 until the expiration of the '808 patent on September 1, 2015, and are permanently enjoined from directly or indirectly engaging in the commercial manufacture, use, marketing, sale, or offer for sale within the United States, or from importing into the United States, of the product which is the subject of the Mylan Defendants' ANDA No. 91-646 until the expiration of the '098 patent, the '539 patent, the '430 patent, the '589 patent, the '476 patent, the '161 patent, the '847 patent, and the patent '898 patent on May 24, 2014;

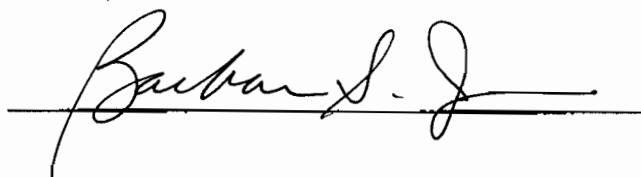
13. IT IS FURTHER ORDERED THAT nothing in this FINAL JUDGMENT ORDER shall be construed to limit the rights of the parties pursuant to 35 U.S.C. § 271(e)(1);

14. IT IS FURTHER ORDERED that the Sandoz Defendants and the Mylan Defendants do not waive any rights to appeal any portion of this final judgment



including the injunctive relief granted, to the extent the Court's findings or holdings are modified on appeal; and

15. IT IS FURTHER ORDERED that any request for costs pursuant to Fed. R. Civ. P. 54(d)(1) and Local Civil Rule 54.1 shall be filed within forty-five (45) days of entry of this FINAL JUDGMENT ORDER, and any motion for attorneys' fees pursuant to Fed. R. Civ. P. 54(d)(2) and 35 U.S.C. § 285 shall be filed within forty-five (45) days of entry of this FINAL JUDGMENT ORDER. The Sandoz Defendants' and the Mylan Defendants' opposition to any request for costs pursuant to Fed. R. Civ. P. 54(d)(1) and Local Civil Rule 54.1 shall be filed within ninety (90) days of the filing of such request, and the Sandoz Defendants' and the Mylan Defendants' opposition to any motion for attorneys' fees pursuant to Fed. R. Civ. P. 54(d)(2) and 35 U.S.C. § 285 shall be filed within ninety (90) days of the filing of such motion. Plaintiffs' reply in support of any motion for attorneys' fees shall be filed within thirty (30) days of the filing of opposition by the Sandoz or Mylan Defendants.

A handwritten signature in black ink, appearing to read "Barbara S. Jones", is written over a horizontal line.

Hon. Barbara S. Jones, U.S. District Court Judge